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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,332	05/15/2001	Grigoriy S. Tchaga	CLON-056CIP	2176

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,332

Applicant(s)

TCHAGA ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. Claims 1-28 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-8 and 14, drawn to metal ion affinity peptides of formula 1, as found in Claim 1, and fusion proteins, classified in class 530, subclass 300.
 - II. Claims 1, 9, and 14, drawn to metal ion affinity peptides of formula 2, as found in Claim 1, and fusion proteins, classified in class 530, subclass 300.
 - III. Claims 1 and 10-14, drawn to metal ion affinity peptides of formula 3, as found in Claim 1, and fusion proteins, classified in class 530, subclass 300.
 - IV. Claims 15-19 and 26-28, drawn to polynucleotides encoding metal ion affinity peptides of formula 1, vectors, host cells, and kits for purifying proteins, classified in class 536, subclass 23.1.
 - V. Claims 15-19 and 26-28, drawn to polynucleotides encoding metal ion affinity peptides of formula 2, vectors, host cells, and kits for purifying proteins, classified in class 536, subclass 23.1.
 - VI. Claims 15-19 and 26-28, drawn to polynucleotides encoding metal ion affinity peptides of formula 3, vectors, host cells, and kits for purifying proteins, classified in class 536, subclass 23.1.
 - VII. Claims 21-25, drawn to methods of purifying fusion proteins having a metal ion affinity peptide of formula 1, classified in class 530, subclass 413.
 - VIII. Claims 21-25, drawn to methods of purifying fusion proteins having a metal ion affinity peptide of formula 2, classified in class 530, subclass 413.
 - IX. Claims 21-25, drawn to methods of purifying fusion proteins having a metal ion affinity peptide of formula 3, classified in class 530, subclass 413.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I-III are drawn to peptides related by virtue of their function – metal ion affinity. This function is governed by structures, each of which is distinct among the three Groups. Since metal ion affinity peptides are not novel in themselves, it is precisely this structure that defines the Groups. These structures are distinct by virtue of their particular characteristics, the amino acid sequences. Thus, Groups I-III are patentably distinct. Although these three Groups are identically classified, a search of any one Group is not co-extensive with the others since the unique structural features must be searched. Thus, to search any two of these Groups together would unduly burden the Office.

Groups IV-VI are drawn to polynucleotides encoding the metal ion affinity polypeptides described as distinct above; Groups VII-IX are drawn to methods of purifying fusion proteins described as distinct above. Groups IV-VI are distinct, each from the other, for the reasons noted above for the encoded peptides. Groups VII-IX are distinct, each from the other, as methods of using the fusion proteins for the reasons noted above for the peptides containing the affinity peptides.

The metal ion affinity peptides of Groups I-III are related to the polynucleotides of Groups IV-VI by virtue of the fact that the polynucleotides encode the metal ion affinity peptides. The polynucleotides have utility for the recombinant production of the peptide and its fusion polypeptides in a host cell. Although the polynucleotides and the peptides are related, they are distinct inventions because the peptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, polynucleotides can be used for processes other than the production of peptides, such as nucleic acid hybridization

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assays. Therefore, Groups I-III are patentably distinct from Groups IV-VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I-III are related to Groups VII-IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the fusion proteins can be used in a materially different process of using that product, such as in enzyme activity assays. Thus, Groups I-III are patentably distinct from Groups VII-IX. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV-VI are related to Groups VII-IX by virtue of the fusion protein used in the methods being encoded by the polynucleotides. However, the polynucleotides are neither used nor made in the methods. Thus, Groups IV-VI are patentably distinct from Groups VII-IX. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The Examiner notes that if Groups I, II or III are found directed to an allowable product, then Groups VII, VIII, or IX, respectively, which are directed to processes of using the

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patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. A telephone call was made to Bret Field on September 23, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



KMK

September 23, 2002